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DISCLAIMER

The safety devices and other controls provided in this equipment will perform reliably when operated, maintained, and repaired in accordance with the instructions of this manual.

Safety devices must be checked periodically and reset, repaired, or replaced as necessary to ensure that they will operate reliably. Equipment and parts that are broken, missing, badly worn, distorted or contaminated should be replaced with appropriate GUIDO RAYOS X parts. The equipment or its components should not be modified without the approval of the manufacturer.

The Manufacturer disclaims all responsibility for any malfunction of this equipment resulting from faulty operation, maintenance or repair, or if any of its components are damaged or modified by anyone other than the manufacturer.

SYMBOLS

SYMBOL	DESCRIPTION
	In compliance with the required european norms CEI 601-1-2 y CEI 601-1
	Altern current
	Attention, read the attached documents
	Fuse
	Off
	On

SPECIFICATIONS

Description	Radiant warmer
Model	NESTOMAT 6050
Alimentación	External AC : 220 V ó 125 V 50/60 Hz
Consumo	AC 0,25 A
Air control temperature	YES
Air temperature range	20 - 40 °C
Air temperature digital readout	YES
Patient temperature control	YES
Patient temperature range	20 - 40 °C
Patient temperature digital readout	YES
Electrostatic discharges protection	Class : I Type : BF
Fuses	Internal : 1 of 2A External : 3 of 2A and 3 of 5A
Operation modes	Preheating Air control mode Servo control mode
Special functions	Oxygen
Alarms	Air sensor, skin sensor, oxygen sensor, high or low temperature, high or low oxygen concentration, power failure, heating failure, motor error.
Optional	Phototherapy assembly, resuscitation/aspiration assembly, shelf monitors, instruments shelf, holding assembly for two gas cylinders, oxygen tent hood with security valve, oxygen servoregulator, head frame, tray for X-ray cassettes, drawer assembly.

I. DESCRIPTION

The NESTOMAT Radiant Warmer provide a controlled source of radiant heat and illumination. The heat is generated by one 500 watt quartz heat tube located above the procedure table. The diverging energy emitted from the heating element is reflected back toward the table surface with a parabolic reflector, this one focuses the diverging waves of energy into parallel waves which are aimed toward the patient.

A lamphouse contains one standard 20 watt halogen lamp for illumination of the work area.

I.1 PATIENT BED. POSITIONING OF PATIENT.

The infant should be placed on the procedure table directly on the mattress or with a single cloth covering between the infant and the mattress cover. The NESTOMAT Radiant Warmer has capability (ten locked positions) to place the head up or the head down. Grasp the locking puller and pull outwards. Reposition the table and release knob. The table will lock in position. Tilting puller is located under the front side of the table.

The table has hinged, transparent panels on the sides and front which can be positioned upright to retain the infant or downward to ease accessibility to the infant. The air temperature sensor is located at the rear panel.

A space for a X-ray cassette tray is provided at the patient platform; the radiant heater shroud can be swivelled, during operation, to allow X-ray treatments, just only pushing the knob located in the rear side of the shroud.

I.2 I.V. STAND.

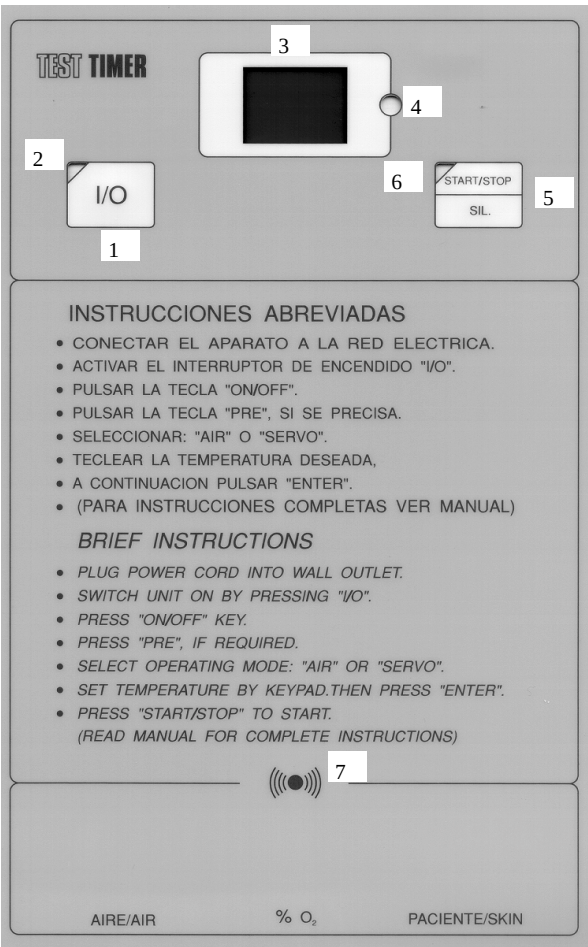
The I.V. stand is mounted in the accessories rear rail, its height is adjustable.

I.3 OPERATION CONTROLS.

All operation controls are located on the front and the rear of the upper column.



(1)	HEAT/CALOR	Indication of heating device operation
	ON/OFF	Switch the heating control
	DISPLAY	Displays information, messages, etc.
(2)	SERVO	Patient Temperature operation mode
	AIR	Air Temperature operation mode
	START/STOP	Start / Stop operation
	1 ... 0	Numerical sensitive keypad
	ENTER	Confirm the set values
	PRE	Preheating
	O ₂	Select Oxygen readout (optional)
(3)	HIGH	High temperature alarm
	LOW	Low temperature alarm
	SENSOR	Sensor failure alarm
	POWER	Power failure alarm
	O ₂	High or Low oxygen alarm
	SIL	Silence alarms

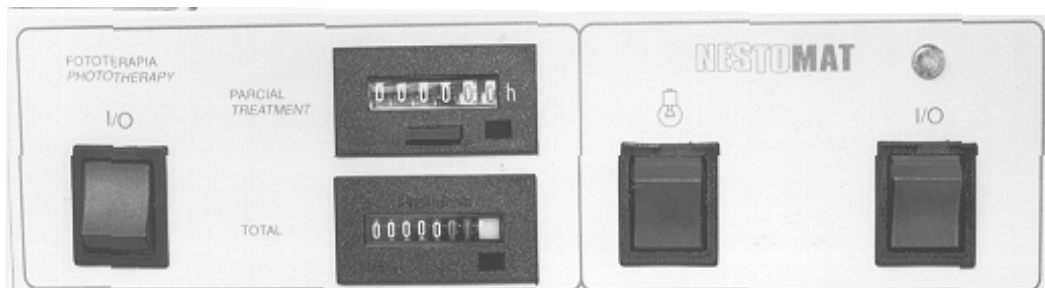


TEST TIMER

1	I/O	Start up of the timer
2		Indication of operation
3	LCD	Display
4		Indicator of timer operation
5	START/STOP SIL.	Start / stop operation and silence alarm
6		Indication of time
7		Audible alarm. End of time

SENSORS

AIRE/AIR	Air temperature sensor
% O ₂	Oxygen sensor (Optional)
PACIENTE/SKIN	Skin temperature sensor



- | | | |
|---|-----|---------------------------------|
| 1 | I/O | Start up phototherapy |
| 2 | | Treatment clock with zero reset |
| 3 | | Total operation clock |
| 4 | | Illumination lamp start up |
| 5 | I/O | NESTOMAT On / Off switch |
| 6 | | Power on led |

II. OPERATION

IMPORTANT: BEFORE TO USE THE **RADIANT WARMER** WITH A PATIENT, IT IS NECESSARY TO CHECK ITS GOOD PERFORMANCE CONDITIONS, AS WELL AS THOSE FROM THE ACCESSORIES AND OPTIONS.

II.1 TO OPERATE

To start operation, plug the cord to the mains (check voltage) and press the **I/O** switch located at the right side of the trolley.

Press the **ON/OFF** key at the front panel, the LCD will display "**GUIDO RAYOS X - VER. x.x**", immediately afterwards the Radiant warmer will perform a selftest of all its circuitry.

II.2 TO PREHEAT

CAUTION: BEFORE TO USE THE **RADIANT WARMER** WITH THE NEWBORN, PREHEAT THE UNIT FOR A BETTER COMFORT OF THE NEWBORN AND AN ACCURATE PERFORMANCE. PREHEATING PERIOD OF TIME DEPENDS ON ENVIRONMENTAL TEMPERATURE. IF PREHEATING MODE IS NOT DESIRED, THE OPERATION MODE, **AIR** OR **SERVO**, CAN BE DIRECTLY SELECTED.

Pressing any key the LCD will display,

AIR= __. __ °C
 SELECT MODE

Press the key "**PRE**" to start the preheating until to reach aproximately the factory preset temperature (28 °C). In the meantime the LCD will display

AT= __. __ °C (__. __ °C)
 PREHEATING

After "=" symbol we can find present temperature.

It is possible to modify preset preheating temperature in order to reach a nearly temperature of the normal operation temperature. Proceed with following steps to change preset preheating temperature:

- Turn on the radiant warmer:

GUIDO RAYOS X
 VER X.X

- Press any key :

AIR=__. _ °C
 SELECT MODE

- Press **AIR** ,

AIR=__. _ °C
 PSET AIR=28.0 °C

- Change old preset 28.0°C temperature to new preheating temperature with numerical keypad.
- By pressing **ENTER**, you will confirm selection ,

AT=__. _ °C
 PRESS START

- Despite it is displayed "**PRESS START**", you have to press "**ENTER**". This is because this is a special feature of NESTORET 5050 .

AIR=__. _ °C
 SELECT MODE

- Finally, press **PRE.** ,

AT=__. _ °C (__. _)
 PREHEATING

Once the preheating temperature is reached, the LCD will display "**UNIT READY**", to be used within a patient, displaying the temperature inside the Radiant warmer as well as advising to the medical personnel by means of an acoustic signal. Then the Operation Mode should be selected just afterwards the newborn is placed into the Radiant warmer.

IMPORTANT: BY PRESSING AGAIN THE **PRE.** KEY, THE **LCD** WILL DISPLAY THE REGISTERED PARAMETERS, SUCH AS **AIR TEMPERATURE (AT)**, **PATIENT TEMPERATURE (ST)**.

NOTE: TO SET **OXYGEN** AND **RELATIVE HUMIDITY** VALUES, SEE CHAPTER **II.5**.

II.3. TO HEAT

If Preheating Mode was not selected, proceed as follows:

Press any key, the LCD will display,

AIR= __. __ °C
SELECT MODE

To select the Operation Mode press AIR or SERVO key. AIR key corresponds to Air Control Mode; SERVO key corresponds to Servo Control Mode (patient skin temperature).

A) AIR CONTROL MODE:

NOTE: THE DIGITAL DISPLAY INFORMS THE TEMPERATURE OF THE AIR WHERE THE NEWBORN IS PLACED.

Pressing **AIR** key, the LCD will display ,

AIR= __. __ °C
PSET AIR= __. __

By means the numerical keypad, set the heating device working range between 20 and 40 °C.

NOTE: WHEN SETTING TEMPERATURE ENTER ALWAYS 3 DIGITS, EVEN IN CASE OF NO DECIMALS. AS EXAMPLE PRESS 3, THEN 7, THEN 0 TO SET 37 DEGRESS.

Then press **ENTER** to confirm, the LCD will display ,

AT= __. __ (__. __)
PRESS START

Then press **START** to start the heating. The heat lamp will indicate the operation of the heating device. By reaching the selected heating range, the heating devices will modulate to keep the temperature stable.

The LCD will display the air registered temperature, as well as will inform, too, the set temperature, displaying **ACTIVED UNIT** to inform the heating device is in operation.

AT=__. °C (__.)
 UNIT ACTIVE

The selected heating range can be modified at any time by pressing **START/STOP** and after **ENTER** key; you will find displayed following message :

AIR=__. °C
 SELECT MODE

Then set the new temperature by the keypad as previously explained and confirm by pressing **ENTER** key. The LCD will display the messages described above. Then press **START** key.

B) SERVO CONTROL MODE:

ATTENTION: BEFORE SELECTING SERVO CONTROL MODE PROCEED TO PREHEAT THE RADIANT WARMER AS EXPLAINED PREVIOUSLY IN THE II.2. TO PREHEAT CHAPTER.

Before anything display on the screen following message :

AIR=__. °C
 SELECT MODE

Press **SERVO** key, the LCD will display ,

SKIN=__. °C
 PSET SKIN=__.

Set the patient temperature between 20 and 40 °C by means of the keypad, confirm by pressing **ENTER** key.

NOTE: WHEN SETTING TEMPERATURE ENTER ALWAYS 3 DIGITS, EVEN IN CASE OF NO DECIMALS. AS EXAMPLE PRESS 3, THEN 7, THEN 0 TO SET 37 DEGRESS.

The LCD will display ,

ST=__. °C (__.)
 PRESS START

NOTE: ST MEANS PRESENT TEMPERATURE. TEMPERATURE IN BRACKETS MEANS PRESET TEMPERATURE.

Then press **START** to start the heating. The heat lamp will indicate the operation of the heating device. By reaching the selected patient temperature, the heating device will modulate to keep the temperature stable.

The LCD will inform the patient temperature and the selected one. By displaying **UNIT ACTIVE** will inform the heating device is on operation.

The set patient temperature can be modified at any time by pressing **START/STOP** and after **ENTER** key; you will find displayed following message :

AIR=__. °C
SELECT MODE

Then set the new temperature by the keypad as previously explained and confirm by pressing **ENTER** key. The LCD will display the messages described above. Then press **START** key.

ATTENTION: IF A MOMENTARY PAUSE WITHOUT CHANGING THE SET PATIENT TEMPERATURE IS REQUIRED, PRESS STOP KEY. PRESS START KEY TO CONTINUE OPERATION. THE RADIANT WARMER WILL OPERATE ON THE SAME OPERATION MODE AND PARAMETERS ALREADY SET.

II.4 TEST TIMER.

This timer has a visual and audible alarms after 1, 5 and 10 minutes (1 + 4 + 5) since it is switched on.

To operate the timer:

- Press I/O key to activate TEST TIMER device.
- Press START/STOP key to initiate first cycle (1 minute).
- When the display shows 1 minute, the device will stop and alarms (visual and audible) will be activated.
- Press START/STOP key to silence alarms and begin next cycle (4 minutes).
- When the display shows 5 minutes, the device will stop and alarms (visual and audible) will be activated.
- Press START/STOP key to silence alarms and begin last cycle (5 minutes).
- When the display shows 10 minutes, the device will stop and alarms (visual and audible) will be activated. Press START/STOP key to silence alarms; the device will be disconnected automatically.

II.5 OXYGEN MONITORING (OPTIONAL).

NESTOMAT 6050 Radiant Warmer monitors the oxygen percentage (optional) when used with a tent hood (optional).

To set the alarm level for above mentioned parameter, proceed as follows (do the calibration with the sensor out of the tent hood, as it has to be done at a concentration of oxygen of 21%, which is the oxygen concentration of air) :

NOTE: WHEN SELECTING YOU MUST START FROM "SELECT MODE" SCREEN.

AIR=__. °C
 SELECT MODE

Press the **O2/HUM** key, the LCD will display ,

AIR=__. °C
 1=OXYG, 2=HUMID

IMPORTANT: OPTION 2=HUMID IS NOT OPERATIVE FOR RADIANT WARMERS.

To set the Oxygen range press **1**, the LCD will display

AIR=__. °C
 OX: 1=PRG, 2=CAL

Then, press **1** again ,

AT=__. °C (__.)
 PRESET OX %=21.0

By means of the keypad set the desired value. Press **ENTER** key to confirm.

Once again you will find following screen :

AIR=__. °C
 1=OXYG, 2=HUMID

Finally press **ENTER** to confirm values.

To calibrate the Oxygen Sensor, press the **O2/HUM**. key, the LCD will display ;

AIR=__. °C

1=OXYG, 2=HUMID

NOTE: ~~DUE TO THE WEAR OF THE OXYGEN CELL SENSOR IT IS~~
RECOMMENDED TO PERFORM PERIODICALLY ITS CALIBRATION PROCEDURES.

~~Check the Oxygen Sensor is plugged on the front panel and its housing is~~
not located inside the Tent Hood, allow to stabilize.

Press **1**, the LCD will display,

AIR= __. __ °C
OX: 1=PRG, 2=CAL

Press **2**, the LCD will display ,

OX CALIBR (21 %)
PRESS ENTER

By pressing **ENTER**, the Oxygen Sensor is already calibrated with a new reference.

New screen displayed ;

AIR= __. __ °C
OX: 1=PRG, 2=CAL

II.6. ALARMS

The NESTOMAT 6050 Alarm System informs to the medical attendant of any incidence may occur. The alarm is visible and audible.

NOMENCLATURE OF SYMBOLS IN ALARM

MESSAGES

- + Excess temperature alarm
- Failing temperature alarm
- = Temperautre O.K.
- * Desactive sensor

A) AIR CONTROL MODE

1. SENSOR ALARM:

In case of air sensor failure or it gets disconnected or out of range; the SENSOR Alarm will activate the corresponding LED and buzzer, the alarm cannot be silenced. The LCD will inform to the attendant displaying ,

* ALARM *
AIR SENSOR

The Radiant warmer is now out of service. Call to any authorized Service engineer.

2. LOW TEMPERATURE ALARM:

Is activated when temperature reaches approximately 1 °C below the preset temperature (See paragraf II.10 to change preset temperature alarm range). "**LOW**" alarm LED will lit, to silence acoustic alarm press SILENCE key. The LCD will display

* ALARM *
AT - RH OX

The alarm can be silenced by pressing the SILENCE key. If SILENCE was pressed and the alarm conditions remain during a period of ten minutes, the alarm will be activated again.

3. HIGH TEMPERATURE

Is activated when the temperature reaches approximately 1 °C higher than the preset temperature (See paragraf II.10 to change preset temperature alarm range). "**HIGH**" alarm LED will lit and the LCD will display ,

* ALARM *
AT + RH OX

to silence acoustic alarm press SILENCE key. If SILENCE was pressed and the alarm conditions remain during a period of ten minutes, the alarm will be activated again.

Check if heat sources are close to the Radiant warmer location, if positive keep them away. If the alarm is still effective unplug the unit from the power source, remove the patient from the radiant warmer and call to the authorised service engineer.

B) SERVO CONTROL MODE

1. SENSOR ALARM:

Informes when a failure of the skin probe or if it gets disconnected or out of range. The Alarm will activate the corresponding LED and buzzer. The LCD will display ,

* ALARM *
SKIN SENSOR

being possible to silence. The Radiant warmer is now out of service. The Radiant warmer can be used on Air Mode if no any circumstances or alarms avoid it, in case it is absolutely needed switch to Air Operation Mode and call to the authorized service engineer.

2. LOW TEMPERATURE

Is activated when temperature reaches approximately 1 °C below the preset temperature (See paragrap II.10 to change preset temperature alarm range). "LOW" alarm LED will lit and the LCD will display,

* ALARM *
ST - RH OX

to silence acoustic alarm press SILENCE key. If SILENCE was pressed and the alarm conditions remain during a period of ten minutes, the alarm will be activated again.

IMPORTANT: CHECK THE CONDITIONS OF THE PATIENT. CHECK THERE IS NOT AIR FLOW IN THE WARD. CHECK THE HEAT LAMP IS ON (THE MICROPROCESSOR CONTROLS THE HEATING DEVICES); IF CONTRARY, UNPLUG THE UNIT FROM THE POWER SOURCE, REMOVE THE PATIENT FROM THE RADIANT WARMER AND CALL TO THE AUTHORISED SERVICE ENGINEER.

3. HIGH TEMPERATURE

Is activated when the temperature reaches approximately 1 °C higher than the preset temperature (See paragrap II.10 to change preset temperature alarm range). "HIGH" alarm LED will lit and the LCD will display ,

* ALARM *
ST + RH OX

to silence acoustic alarm press SILENCE key. HEAT lamp will switch off. If SILENCE was pressed and the alarm conditions remain during a period of ten minutes, the alarm will be activated again.

Check the conditions of the patient. Check if heat sources are close to the Radiant warmer location, if positive keep them away.

If the alarm is still effective, unplug the unit from the power source, remove the patient from the radiant warmer and call to the authorised service engineer.

C) POWER FAILURE

Is activated when failure of the power from the mains. The alarm circuit includes a rechargeable battery and operation conditions of it must be checked periodically.

To switch off the alarm operation, if desired, refer to chapter **II.6. "SENSORS ACTIVATION AND DEACTIVATION"**.

II.7. SENSORS ACTIVATION AND DEACTIVATION

The applications program of the NESTOMAT 6050 Radiant warmer allows to the user, at any moment, to deactivate or activate the sensors of the monitored parameters, if required for calibration procedures or non essential parameters cancellation (Oxygen and/or Relative Humidity).

If the Radiant warmer is switched off, proceed as follows:

Press **I/O** switch, located at the side of the trolley.

Press **ON/OFF** key at the front panel. The LCD will display ,

GUIDO RAYOS X
VER X.X

then type sequentially:

- **SILENCE** key
- 7388
- **SILENCE** key.
- ENTER

then the LCD will display ,

MAINT: 0 SW, 1 LNG
2 SEN, 3 DIS, 4 RNG

Press **2** key and the LCD will display all coded available sensors and their status as follows,

1RH 2AT 3ST 4HT
5FA 6OX 7A2 8AI

(at the right side of each coded sensor "+" or "-" will display, meaning activated or deactivated respectively)

(RH=Relative Humidity - Non operative, AT=Air Temperature, ST=Skin Temperature, HT=Heating Device Temperature, FA=Fan - Non operative, OX=Oxygen - Optional, A2 and A1 are auxiliary options for future implements)

To activate (+) or deactivate (-) press the corresponding figure key of the sensor. Proceed with any sensor you want to activate or deactivate, then press ENTER to

confirm.

The LCD will display ,

MAINT.: 0 SW, 1 LNG
2 SEN, 3 DIS, 4 RNG

pressing again **ENTER** the LCD will display the initial message. You can proceed to set the Operation Mode, etc. as above described.

II.8. SOFTWARE LANGUAGE

The applications program of your NESTOMAT 6050 is delivered from factory in two languages: english and spanish. At factory your radiant warmer has been preset to english, if you want to switch to the language, proceed as follows:

Press **I/O** switch, located at the side of the trolley.

Press **ON/OFF** key at the front panel. The LCD will display ,

GUIDO RAYOS X
VER X.X

then type sequentially:

- **SILENCE** key
- 7388
- **SILENCE** key.
- **ENTER**

then the LCD will display,

MAINT.: 0 SW, 1 LNG
2 SEN, 3 DIS, 4 RNG

Press **1** key

the LCD will display ,

1=ENGLISH VER
2=SPANISH VER

press the corresponding key to the selected language and confirm by pressing **ENTER**.

II.9. CHANGE OF DISPLAY TYPE

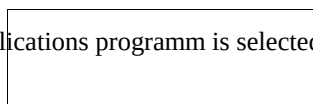
Press 3 key when applications programm is selected, display type will be activated,

1 DISPL 16 CARS
2 DISPL 20 CARS

for LCD equipment press 1; for luminiscent display press 2.

II.10. ON/OFF SWITCH (SW) ACTIVATION

Press 0 key when applications programm is selected. The display will show:



WITH ON/OFF
WITHOUT ON/OFF

For equipments with ON/OFF switch on front panel keypad, press the ON/OFF key, selecting WITH ON/OFF option.

II.11. CHANGE OF TEMPERATURE ALARM RANGE (HIGH / LOW)



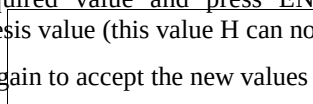
Press 4 key when applications programm is selected. The display will show:

RNG.TMP (0.1 ÷ 2.0)
R= __.__, H=

Preset value of temperature Range (R) (High / low) is 1 °C. To this value corresponds a hysteresis value (H) of 0,4 °C.

To change the preset value (R) (between 0,1 °C and 2,0 °C), by means of the numerical keypad, set the required value and press ENTER, the display will show the corresponding hysteresis value (this value H can not be changed).

Then press ENTER again to accept the new values (R) and (H).



III. MAINTENANCE

For routine cleaning, the entire unit may be wiped with a mild soap and water solution. Avoid scratching painted surfaces. Do not use any cleaning agent containing an abrasive material. When sterilization of exterior parts is necessary, wipe those parts with a cold sterilization agent not including alcohols nor ethers.

IV. OPTIONAL ACCESSORIES.

IV.1. PHOTOTHERAPY ASSEMBLY.

To turn on the Phototherapy , just press the **I/O** switch.

Electric starters allow an immediate switching on.

WARNING: COVER INFANT'S EYES TO PROTECT FROM HIGH LIGHT LEVELS.

Reset the clock to zero when starting the treatment, to know the exact time for each patient.

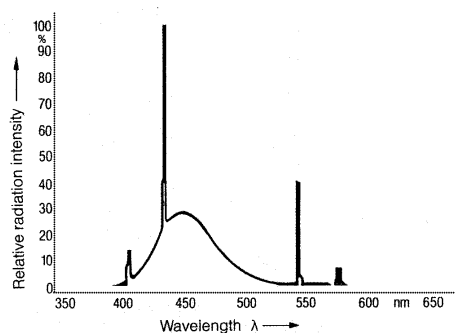
The total time clock will inform the total time that the Phototherapy is being used. In such way the user will know how long the lamps have been operating.

When the treatment time is over or any time the operator wants to interrupt the treatment, press **I/O** to switch off the unit.

Phototherapy assembly comprises four DULUX ® L lamps, specially designed for this kind of treatment.

The electronic starters allow a reliability over 30.000 switching on operations.

The lamps emit at $8 \mu\text{W}/\text{cm}^2/\text{nm}$, measured at 80 cm distance. For an effective treatment, $4 \mu\text{W}/\text{cm}^2/\text{nm}$ are required at least.



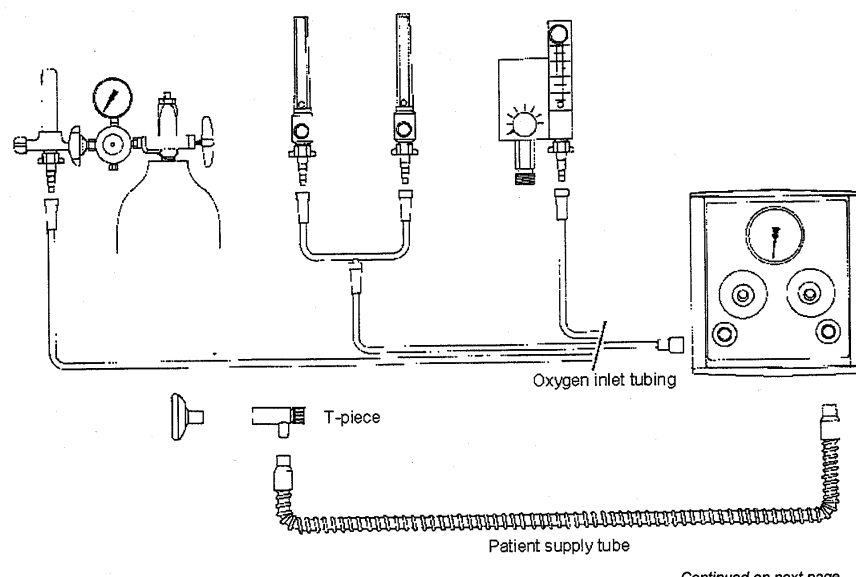
After operation hours the lamps lose gradually their output power, being recommended to check periodically the radiation power with the appropriate measuring equipment. When radiation drops below $4 \mu\text{W}/\text{cm}^2/\text{nm}$, the lamps should be replaced.

IV.2. RESUSCITATION/ASPIRATION ASSEMBLY.

Provided with peak inspiratory pressure control valve and pressure relief back-up valve, manometer gauge, patient circuit. Flowmeter with humidifier and Venturi suction device for aspiration with collecting jar.

Using the NEOPUFF™ Infant Resuscitator

- Please read and understand the instructions fully before using the Neopuff resuscitator and related accessories.
 - The Neopuff resuscitator is to be used only by persons trained in infant resuscitation. It is responsibility of the purchaser to ensure that all users of this device have been adequately trained in resuscitation techniques.
 - The Neopuff resuscitator should only be used after checking that correct pressures will be delivered to the baby.
 - Ensure no smoking, naked flames or sources of ignition are present while the unit is in use.
 - For connection to flow regulated oxygen or oxygen/air mixture only.
 - Minimum recommended operating gas flow 5 l/min. Do not attempt to use a higher flow than 15 l/min.
 - The Maximum Pressure Relief can be adjusted up to a nominal 80 cm H₂O, and should only be done in exceptional circumstances by persons trained in infant resuscitation. Do not attempt to set the Maximum Pressure Relief above 80 cm H₂O.
 - Use only a Fisher & Paykel T-piece.
- 1 Connect flow controlled oxygen or blender oxygen/air supply to the Neopuff Gas Inlet port using oxygen inlet tubing.
 - 2 Connect the patient supply tube to the Neopuff Gas Outlet port. If reusable tubing is used, connect reusable T-piece to the patient, end of patient supply tube.
 - 3 Adjust the oxygen or oxygen/air flow between 5 and 15 l/min. Do not attempt to use a higher flow than 15 l/min.
 - 4 To check the Maximum Pressure Relief setting:
Connect the test lung to the T-piece, and check gas is flowing through the patient

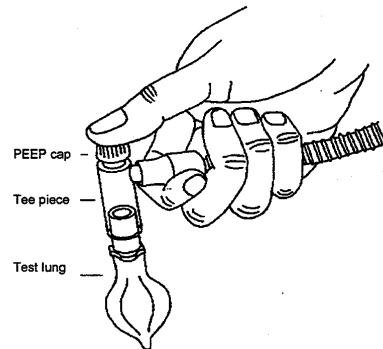


supply tube.

Check that the Circuit Pressure gauge reads zero with the Gas inlet disconnected.

Occlude the small aperture in the Positive End Expiratory Pressure (PEEP) cap on the T-piece with your thumb.

Turn the Inspiratory Pressure (PIP) control clockwise until the manometer needle stops. This may require few rotations due to the fine thread pitch of the valve. The manometer now indicates the current Maximum Pressure Relief



setting.

- 5 To adjust the maximum Pressure Relief:

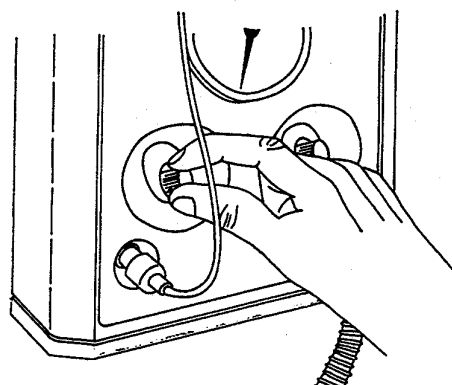
Determine the current Maximum Pressure relief setting as described in step 4 .

Occlude the PEEP cap aperture with your thumb.

Rotate the Maximum Pressure Relief control to the desired Maximum Pressure Relief setting.

- 6 To adjust the Inspiratory Pressure (PIP) valve:

Check the test lung is attached to the T-piece and occlude the PEEP cap aperture



with your thumb.

Adjust the Inspiratory Pressure control knob to the desired peak inspiratory pressure as displayed on the manometer.

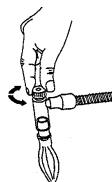
- 7 To adjust the Positive End Expiratory Pressure (PEEP) valve:

Remove your thumb from the PEEP cap aperture to allow gas to flow through

the PEEP valve.

Adjust the PEEP cap to set the desired PEEP level as displayed on the manometer.

- 8 Remove the test lung from the T-piece. Fit the desired neonatal resuscitation mask or endotracheal tube to the T-piece. The Neopuff resuscitator is now ready for



use.

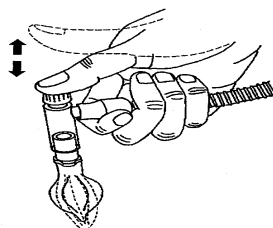
- 9 Place the mask over the baby's mouth and nose, or insert the endotracheal tube into the baby's airway.

- 10 To resuscitate:

Place your thumb over the PEEP cap aperture on the T-piece to produce an inspiration.

Remove your thumb from the PEEP cap aperture on the T-piece to allow an expiration.

Cleaning.



Ensure all oxygen and air supplies are turned off and disconnected from the Neopuff before performing cleaning procedures.

Clean the Neopuff and accessories either weekly or between babies.

Do not use solvents, alcohol-based, or abrasive cleaning solutions.

Ensure all parts and accessories are checked before returning the device to service.

For ethylene oxide gases: Some carrier gases can cause stress cracking and are not

	Neopuff	Test lung	Mask	Supply tube	T-piece
Steam autoclavable 136 °C / 220 kPa / 4 minutes			✓	✓	✓
Steam autoclavable 120 °C / 96 kPa / 15 minutes			✓	✓	✓
Ethylene Oxide Gas		✓	✓	✓	✓
Chemical liquid immersion				✓	✓
Wipe with soft damp cloth	✓				

suitable. If in doubt check with chemical supplier.

For chemical liquid immersion: Some chemicals can be harmful to plastics. If in doubt check with chemical supplier.

There are no user serviceable parts inside this device.

Maintenance.

Only qualified personnel should carry out service and maintenance procedures.

After any maintenance is completed, ensure the equipment is functioning correctly in accordance with the published performance specifications.

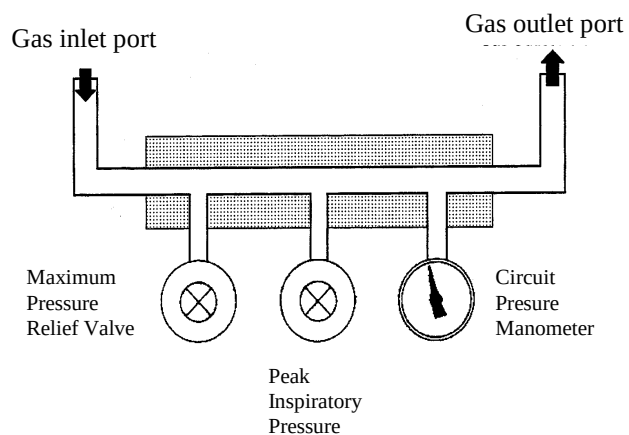
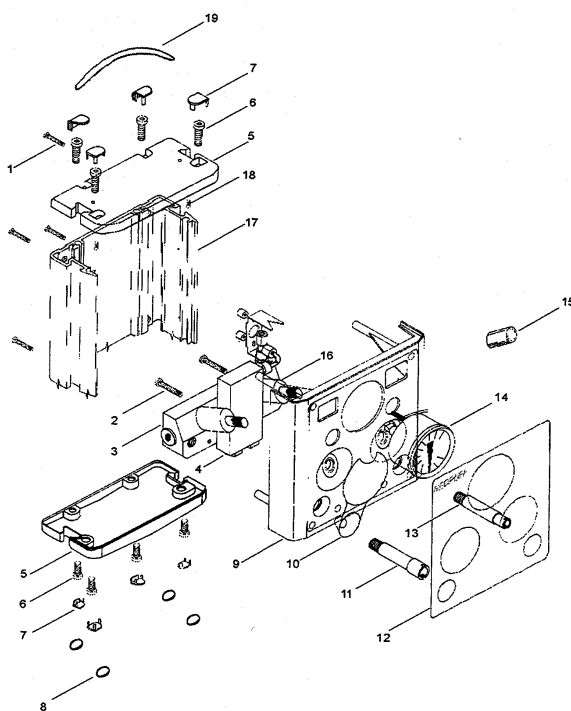
Disassembly

- Remove the front panel, fixed by four screws.
- remove gas inlet and outlet connectors using torque driver and special adaptor.
- Unscrew two manifold retaining screws at bottom of unit.
- Disconnnet monometer tube at top of T-connector by pushing down on collar of T-connector and pulling tube free.
- Remove manifold assembly.

Replacing valve assembly

- Disassemble Neopuff as aoutlined above.
- Remove the inspiratory valve assembly using the C-spanner. Valve unscrews anti-clockwise.
- Fit new inspiratory valve assembly, tighten clockwise with C-spanner. The inspiratory valve assembly can be identified by the shite restrictor plug located at the bottom end of the valve.
- remove maximum pressure relief valve assembly using C-spanner. Unscrews anti-clockwise.
- Fit new maximum pressure relief valve assembly, tighten clockwise with C-spanner. The masimum pressure relief valve has not restrictor plug.
- Reassemble Neopuff and calibrate.

The manometer is not a serviceable item and must be replaced by Manometer kit complete.

Functional schematicAssembly diagram

ITEM	REF.	DESCRIPTION
1	616050011	Screw # 8 x 1" Csk Hd.
2	614040153	Screw # 8 x 1" Pan Hd.
3	500RD007	Manifold block
4	500RD519	Reservoir
5	693040741	End cap
6	614040309	Screw M8 x 20
7	693040706	Plug set of 5
8	693041436	Foot
9		Panel plastic
10	043041057	Cover, max pressure relief.
11	500RD509	Connector 10 mm female gas inlet
12		Front fascia
13	500RD508	Connector 10 mm male gas outlet
14	500RD554	Manometer kit
15	693041444	Cap, inspiratory pressure valve
16	500RD506	Valve assemblies, pair
17	641040816	Column
18	614040117	Screw M4 x 8 Pan Hd
19	641040809	Handle

Product specifications

Manometer Range	- 20 a 80 cm H ₂ O
Maximum Pressure Relief	Between 70 and 84 cm H ₂ O
Caudal de entrada de gases Input Gas flow Range	Between 5 and 15 l/min
Peak inspiratory pressure (@ 10 l/min)	2 to 80 cm H ₂ O
PEEP (@ 10 l/min)	2 to 15 cm H ₂ O
Recommended body weight range	Up to 10 kg

IV.3. SHELVES

Shelf for monitors.

Shelf for instruments.

Those shelves can be installed in both sides of the unit and its height can be regulated, using the accessories rail placed on the rear of the column.

IV.4. OTHER OPTIONAL ACCESSORIES

Tray for X-ray cassettes.

Oxygen tent hood with security valve.

Holding assembly for two gas cylinders.

Drawers assembly.

IV.5 PULSEOXIMETRY MODULE.

The NESTOMAT 6050 (6100 Version) is a Neonatal Care Center that noninvasively and continuously monitors arterial blood oxygen saturation (SaO₂) and pulse rate.

SaO₂ and pulse rate information is conveyed both visually and audibly. A custom high contrast Liquid Crystal Display (LCD) with backlighting indicates the SaO₂, pulse rate, pulse signal strength and system messages. The tone generator "beeps" with each pulse beat. The pulse "beep" momentarily changes to a lower tone "beep" when there is a decrease in SaO₂.

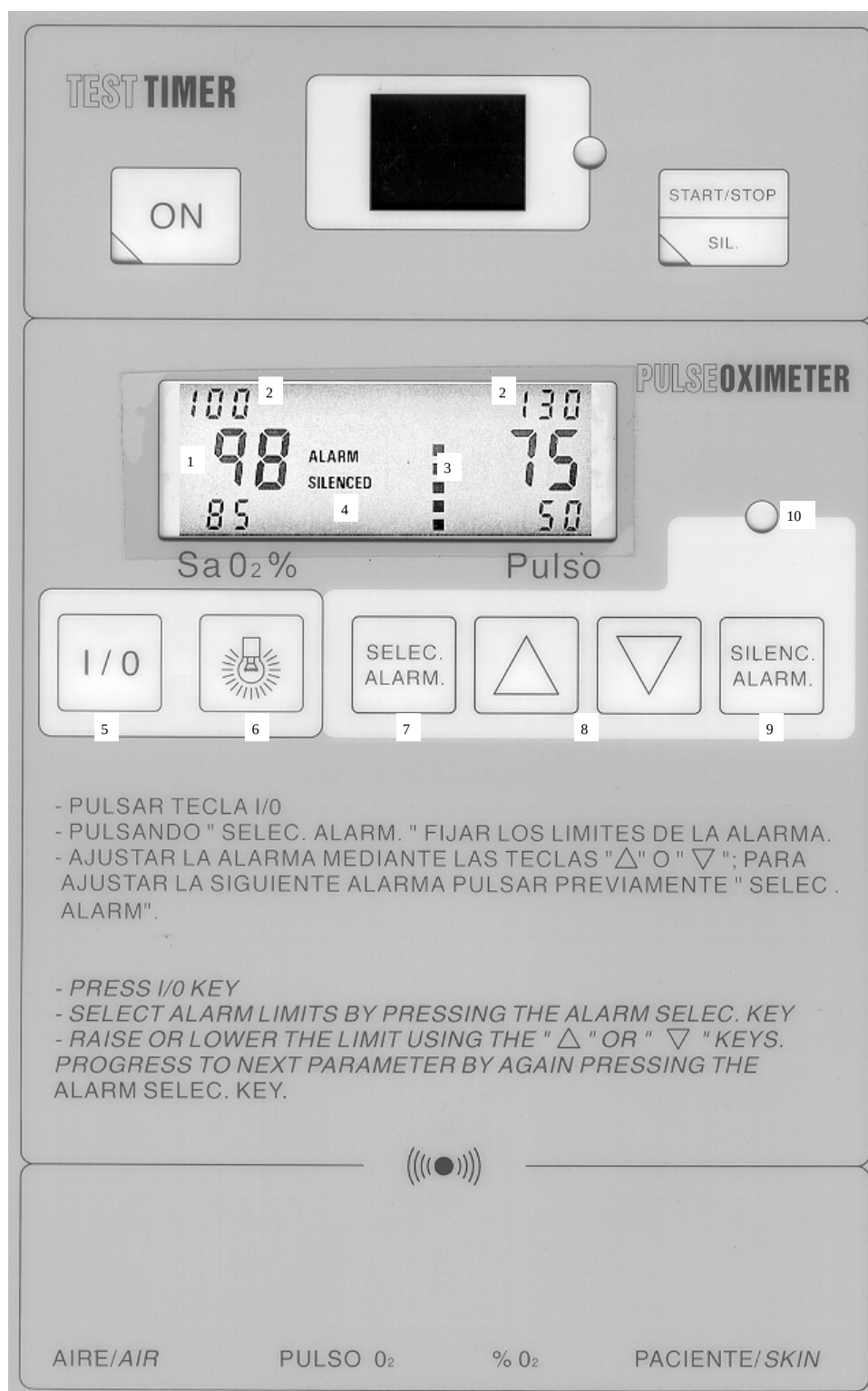
It has a flexible alarm system with audible and visual indicators. The high and low alarm limits are user adjustable. The audible alarm and pulse "beep" volume can be adjusted or inhibited by the user.

Theory of Operation

The NESTOMAT 6050 (6100 Version) determines SaO₂ and pulse rate by passing two wavelengths of light, one red and one infrared, through body tissue to a photodetector. Pulse identification is accomplished by using plethysmographic techniques, and oxygen saturation measurements are determined using spectrophotometric oximetry principles. During measurement, the signal strength resulting from each light source depends on the color and thickness of the body tissue, the sensor placement, the intensity of light sources and the absorption of the arterial and venous blood (including the time varying effects of the pulse) in the body tissues.

The NESTOMAT 6050 (6100 Version) processes these signals, separating the time invariant parameters (tissue thickness, skin color, light intensity and venous blood) from the time variant parameters (arterial volume and SaO₂) to identify the pulse and calculate the oxygen saturation. Oxygen saturation calculations can be performed because blood saturated with oxygen predictably absorbs less red light than oxygen depleted blood.

Since measurement of SaO₂ depends on a pulsating vascular bed, any condition which restricts blood flow, such as use of a blood pressure cuff



or extremes in systemic vascular resistance, may cause an inability to determine accurate pulse and SaO₂ readings.

Front Panel Displays, Indicators and Keys.

1) SaO₂ and Pulse Rate

Both are shown in large numerals. Smaller numerals show the high alarm limit (above) and low alarm limit (below) each display.

2) Triangular Indicators

The triangular indicators point to the alarm limits to indicate the alarm is selected for setting or flash to indicate the alarm limit has been violated. "H" indicates high and "L" indicates low alarm limit.

3) Bargraph

The vertical bargraph has eight segments to display pulse activity and strength. The bargraph is logarithmically scaled to indicate a wide range of pulse strengths.

4) Low Pulse

The pulse level is low enough that the reading may be unreliable. May indicate improper probe positioning.

Pulse Search

The unit is automatically adjusting signal processing and probe LED drive levels to achieve acceptable signal levels, and is interpreting the signal to detect the pulse.

Alarm

This indicates the alarm volume is being adjusted with the Up/Down arrow keys.

Beep

This indicates the pulse "beep" volume is being adjusted with the Up/Down arrow keys.

Alarm Silenced

Flashing indicates the alarm has been silenced with automatic two minutes reset. Non-flashing (continuous) indicates the alarm has been silenced indefinitely.

Beep Silenced

This is displayed for 1-2 seconds when the pulse "beep" volume is adjusted to off.

Check Sensor

The probe is off the patient, needs to be repositioned, or is not connected to the unit.

5) I/O

This key turns the Pulseoximetry Operating Mode on and off.

6) Display Light (Bulb)

This toggles the display backlight on and off.

7) Alarm Selec.

Press Alarm Selec. to step through or set each of the four alarm limits. Pressing a fifth time sets the monitor at none selected. If neither the Up/Down arrows nor the Alarm Selec. key are pressed for approximately 20 seconds, the system returns to none selected.

8) Up/Down Arrows

When an alarm limit is not selected, these keys increase/decrease either the alarm volume (when the alarm is not silenced) or the pulse "beep" volume (when the alarm is silenced). When an alarm limit is selected, these keys control scrolling up and down through the alarms limits setting.

9) Alarm Silence

Pressing this key turns the audible alarm off either for two minutes or until the key is pressed again. Pressing and holding it for 3 seconds turns the alarm off until the key is pressed again or the I/O is turned off and on.

10) Alarm LED

Indicates a patient or system alarm. The LED flashes or remains steady depending on the alarm condition (See Alarms and Indicators Chapter).

Alarms and Indicators

1) Patient:

- *Pulse beat detection*: A short "beep" sounds each time a pulse beat is detected. The volume is adjustable (including off) independently from the alarm volume.
- *Matched or Exceeded Alarm Limit*: A two-tone alarm sounds (when the alarm is not silenced), the red Alarm LED flashes, and the triangular indicator for the violated alarm limit flashes.
- *Low Pulse Amplitud*: LOW PULSE is displayed.
- *Drop in SaO2*: A lower-tone "beep" sounds.

2) System:

- *Probe Off patient or not connected to unit*: A double "beep" sounds every second (when the alarm is not silenced), CHECK SENSOR is displayed and the red alarm LED lights continuously.
- *Searching too long for Pulse*: A double "beep" sounds every second (when the alarm is not silenced), PULSE SEARCH is displayed and the red alarm LED lights continuously.

Starting Pulseoximetry

WARNING: OPERATION OF PULSEOXIMETRY MAY BE AFFECTED IN THE

PRESENCE OF STRONG ELECTROMAGNETIC SOURCES, SUCH AS ELECTROSURGERY EQUIPMENT. OPERATION MAY BE AFFECTED IN THE PRESENCE OF IMAGING EQUIPMENT, SUCH AS MAGNETIC RESONANCE IMAGING, COMPUTED TOMOGRAPH DEVICES, ETC. SIGNIFICANT LEVELS OF DISFUNCTIONAL HEMOGLOBINS, SUCH AS CARBOXYHEMOGLOBIN OR METHEMOGLOBIN, WILL AFFECT THE ACCURACY OF THE SaO_2 MEASUREMENT. OPERATION MAY BE AFFECTED IN THE PRESENCE OF HIGH AMBIENT LIGHT. SHIELD THE PROBE AREA IF NECESSARY.

~~Connect the patient cable to the PATIENT CABLE/PROBE connector at the bottom of the front label of the equipment, just below the user instructions.~~

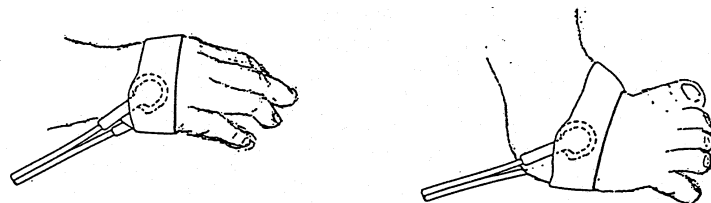
Connect the probe to the Patient Cable.

Press the front panel I/O key. It performs a self test and lights all legends when turned on.

Upon completion of the self test (approximately 2 seconds), the unit will automatically enter the monitoring mode.

NOTE: UPON POWER-UP THE UNIT DEFAULTS TO AN EIGHT (8) PULSE AVERAGING MODE FOR SaO_2 MEASUREMENT AND AN EIGHT (8) SECOND AVERAGE FOR PULSE MEASUREMENT.

Attach the Universal "Y" probe to the patient as shown in figure here below, using adhesive strips as necessary. ~~When using the Universal "Y" probe on the finger, attach the LED (light source) portion of the sensor to the finger nail side of the finger.~~



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probe is attached to the patient, allow several pulse beats for the monitor to stabilize. Observe the pulse bargraph located on the LCD display. If the pulse signal strength is low, the probe position may need adjustment.

Measuring the Pulse Rate and SaO_2

After approximately four or five pulse beats, the Pulse Rate and SaO_2 values are displayed.

The pulse "beep" sounds with each pulse beat when the pulse tone is enabled. A lower-tone "beep" sounds when a drop in SaO_2 is detected.

Setting and Interpreting Alarms

Alarms are still active while setting, but the "H" and "L" triangular indicators do not flash for violated alarms. Both indicators act as a cursor to identify the limit selected for adjustment.

Press the ALARM SELEC. key until the cursor is positioned at the alarm parameter you are setting (High SaO₂, Low SaO₂, High Pulse Rate, Low Pulse Rate).

Press the Up/Down arrow keys to increase or decrease the selected alarm value. "--" in the alarm display indicates the alarm parameter is set to OFF.

NOTE: THE ALARMS ARE NOT OVERLAPPING, YOU CANNOT SET THE LOW ALARM HIGHER THAN THE HIGH ALARM OR THE HIGH ALARM LOWER THAN THE LOW ALARM.

When an alarm limit is violated, a two-tone alarm sounds (when the alarm is not silenced), the red alarm LED flashes and the triangular indicator for the violated alarm limit flashes. The alarms stop when the alarm limit is no longer violated.

Press the Alarm Silence key to silence the alarm for two (2) minutes. ALARM SILENCED flashes on the display. Press the Alarm Silence key again to end the two minute alarm silence.

Press and hold the Alarm Silence key for three (3) seconds to silence the alarm indefinitely. ALARM SILENCED is displayed continuously. Press the Alarm Silence key again to end the indefinite alarm silence mode.

LOW PULSE is displayed when the pulse amplitude is low.

A lower-tone "beep" sounds when a drop in SaO₂ is detected.

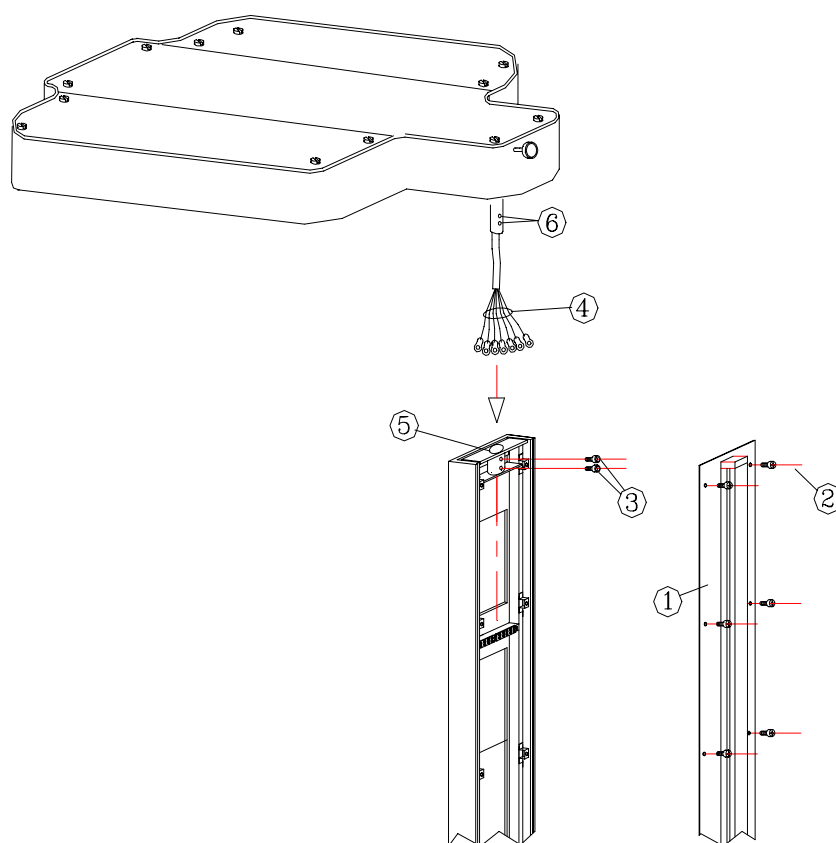
Adjusting the Audio Volume

- Alarms: Use the Up/Down arrow keys to adjust the audio alarm volume (when not setting the alarm limits and the alarm is not silenced).
- Pulse "Beep": Silence the audio alarms by pressing the Alarm Silence key (be sure ALARM SILENCED is displayed). Now use the Up/Down arrow keys to set the pulse beep volume reaches off.

V. INSTALLATION

To carry out the installation of NESTOMAT Radiant Warmer, following steps must be executed:

1. Remove the rear lid of the column ① unscrewing the screws ②.
2. Unscrew the screws ③.
3. Introduce the radiant heater device with the cables ④ through the bushing ⑤.
4. Place the radiant heater device, taking care that the blind holes ⑥ are in front of the holes where the screws ③ are positioned.
5. Replace the screws ③ and tighten them firmly.
6. Connect the cable ④ as per electric diagram in page 35.
7. Replace the rear lid ① and replace the screws ②.



VI. SERVICE.

Service must be performed by qualified and authorized service personnel. Call to the manufacturer or its Agent for any service you may require.

VI.1 INSTRUMENTS REQUIRED.

To perform the adjustments properly the following instruments are required:

- Digital Voltmeter (DVM).
- Temperature and Oxygen Concentration Simulator (SIM60TO).
- Screwdriver for adjusting (trimmer).

VI.2. ADJUSTMENTS

Before to perform the adjustments, check the voltage from the mains and from the poser supply.

Input voltage should be 16 ± 2 V c.a. between 1 and 2 at J14.

Here below are detailed power referenced to ground (**GND -TP8**):

Power	Test point
+ 5 V	TP6
+ 15 V	TP7

Once checked, perform the adjustment according to the instructions detailed here below.

- Put DVM probes between **GND-TP8** and **TP3**.
- Twist **P6** Potentiometer to read 0 Volts.
- Put DVM probes between **GND-TP8** and **TP4**.
- Twist **P7** Potentiometer to read 1.250 mV.
- Deactivate sensors on the Service Menu.
- Turn off the Incubator by pressing the **I/O** Switch located at the rear side of the unit.
- Release the connectors **J1, J6, J12**.
- Connect on above connectors the wires from the Temperature Simulator (**SIM60TO**) as follows:

Cable	Connector	Function
1	J7	Air temperature
2	J8	Patient temperature
3	J9	Oxygen concentration

Turn on the Radiant Warmer by pressing the I/O Switch located at the rear side of the trolley.

Press the ON/OFF key.

Press three times the "PRE." key.

The LCD will display :

AT=00.0	PT=00.0
OX=00.0	RH=00.0

(AT: Air Temp., PT: Patient Temp., OX: Oxygen, RH: Non operative parameter)

A. Air Temperature

- Place a jumper at J15.
- Set Simulator switch at "0".
- Set DVM probes between **GND-TP8** and **TP1**. Twist **P1** Potentiometer to read between 2 to 4 mV.
- Set Simulator switch at "40/99".
- Twist **P2** Potentiometer to read 40.0 °C at the Air Temperature Display on the Incubator Control.
- Set Simulator switch at "18/21".
- Twist **P1** Potentiometer to read 18.0 °C at the Air Temperature Display on the Incubator Control.

Because adjustments are mutual interactive, therefore have to be repeated steps 3 and 6 until to get the correct value.

B. Patient Temperature

- Set Simulator switch at "0".
- Set DVM probes between **GND-TP8** and **TP2**. Twist **P5** Potentiometer to read between 2 to 4 mV.
- Set Simulator switch at "40/99".
- Twist **P4** Potentiometer to read 40.0 °C at the Air Temperature Display on the Incubator Control.
- Set Simulator switch at "18/21".
- Twist **P5** Potentiometer to read 18.0 °C at the Air Temperature Display on the Incubator Control.

Because adjustments are mutual interactive, therefore have to be repeated steps 3 and 6 until to get the correct value.

C. Oxygen Concentration

- Set Simulator switch at "0".
- Set DVM probes between **GND-TP8** and **TP5**. Twist **P9** Potentiometer to read 5 mV maximum.

-
- Set Simulator switch at "40/99".
 - Twist **P8** Potentiometer to read 99.0% at the Oxygen Concentration Display on the Incubator Control.
 - Set Simulator switch at "18/21".
 - Twist **P9** Potentiometer to read 21.0% at the Oxygen Concentration Display on the Incubator Control.

Because adjustments are mutual interactive, therefore have to be repeated steps 3 and 6 until to get the correct value.

Once all adjustments are performed, proceed as follows:

- Turn off the Radiant Warmer by pressing the I/O Switch located at the rear side of the trolley.
- Disconnet the jumper placed at J15 (point 1 - Air temperature).

NOTE: IT IS VERY IMPORTANT NOT TO FORGET TO DISCONNECT THIS JUMPER. IF YOU DO NOT DISCONNECT IT AND WHEN THE UNIT IS WORKING, IT IS DICONNECTED THE AIR TEMPERATURE SENSOR THE UNIT WILL SWITCH OFF.

- Release the Simulator.
- Connect all sensors wires on their locations.
- Turn on the Radiant Warmer by pressing the I/O Switch and the ON/OFF key.
- Activate on the Activation/Deactivation option all those available sensors on the Radiant Warmer (Paragraph II.6).
- Turn off the Radiant Warmer and then Turn on again to make all the above effective.

ELECTRONIC DIAGRAM

PEGAR AQUI ESQUEMA DE
NESTOMAT 6050 REV 1.2,
QUE ESTA DENTRO DEL
MANUAL ORIGINAL EN EL
ARMARIO

NUMBER	REF.	DESCRIPTION	VALUE		
1		RESISTOR	4K7	1/4 W	R6, R10,R15, R19, R20, R21,R32,R39, R43,R44, R49
2		RESISTOR	10K	1/4 W	R5, R9, R14, R17, R24, R36, R45
3		RESISTOR	1K	1/4 W	R22
4		RESISTOR	680 Ω	1/4 W	R34, R35, R37, R40, R41, R42, R48
5		RESISTOR	100K	1/4 W	R13, R16, R30, R31, R50
6		RESISTOR	75 Ω	1/4 W	R3, R25
7		RESISTOR	18K7	1/4 W	R2, R33
8		RESISTOR	470 Ω	1/4 W	R7, R38
9		RESISTOR	2K2	1/4 W	R11, R26, R27, R46
10		RESISTOR	487 Ω	1/4 W	R1, R28
11		RESISTOR	1K5	1/4 W	R8
14		RESISTOR	330 Ω	1/4 W	R4
15		RESISTOR	2K	1/4 W	R47
16		RESISTOR	75K	1/4 W	R23, R18
17		RESISTOR	22K	1/4 W	R12
18		SQUARE CONECTOR 2 PIN R2,54			J2, J12, J4
19		SQUARE CONECTOR 3 PIN R2,54			J1, J6
20		SQUARE CONECTOR 2 PIN R3,96			J13, J14
21		3 WAY BREAKAWAY			J7, J8, J9, J10, J11
22		2 WAY BREAKAWAY			J15
23		DOUBLE ROW TIRA 7 WAY BREAKAWAY			J5
24		BOARD 9 WAY BREAKAWAY			CN3
25		CHOKE			CH1
26		CAPACITOR	150 pF		C11
27		CERAMIC CAPACITOR	100 nF		C1, C2, C4, C8, C9, C12, C13, C14, C15, C18, C20, CD1, CD2, CD5, CD6, CD7
28		CERAMIC CAPACITOR	27 pF		C5, C6
29		CERAMIC CAPACITOR	10nF		C7
30		RADIAL CAPACITOR	1 μ F	100 V	C3
31		RADIAL CAPACITOR	100 μ F	35 V	C21
32		TANTALIUM CAPACITOR	10 μ F	16 V	C10
33		RADIAL CAPACITOR	470 μ F	16 V	C17
34		RADIAL CAPACITOR	2200 μ F	16 V	CD8, C19
35		RADIAL CAPACITOR	4700 μ F	25 V	C16
36		DIODE 1N4148			D1, D2,, D3, D4, D5, D6
37		POTENCIOMETER	1K		P6, P7
38		POTENCIOMETER	5K		P3
39		POTENCIOMETER	10K		P1, P2, P4, P5, P8, P9
40		TRANSISTOR	BC 548		Q1, Q4, Q5, Q6
41		TRANSISTOR	BC 557		Q3
42		TRANSISTOR	BC 337		Q2
43		TRANSISTOR	AD 580		RE1
44		CRISTAL 12 MHZ			X1
45		TEST POINTS			TP1, TP2, TP3, TP4, TP5, TP6, TP7, TP8
44		CERAMIC RESISTOR	50 Ω	4 W	R53
45		RECTIFICATOR BRIDGE	B80	1500	PR1

NUM. ORDEN	REF.	DESCRIPCION	VALOR	
46		RELAY	12 V	RL1
47		FUSEHOLDER	2A	F1
48		REGULATOR 7805		RE 2
49		REGULATOR 7815		RE 3
51		BUZZER		Z1
52		74C923		U1
53		74HC573		U6
54		ADC0801		U7
55		CA 3140		U3, U4, U9
56		AD202JN		U5
57		CD4051		U8
58		SOLID STATE RELAY		RL2
59		DISIPATOR L-200 20x20		RE2
60		FIXED RED LED		L2, L3, L4, L5, L6, L8
61		INTERMITTENT RED LED		L1
62		FIXED GREEN LED		L7
63		40 PIN SOCKET		U2
64		16 PIN SOCKET		U8
65		20 PIN SOCKET		U1, U6, U7
66		8 PIN SOCKET		U3, U4, U9
68		ARRAY	8x4K7	AR1, AR2
69		MICROPROCESATOR	DS5000	U2
70		DISPLAY CG57103		

WARRANTY

GUIDO RAYOS X S.A. (hereinafter referred to as GRX) warrants that each NESTOMAT Radiant Warmer will be free from defects in material and workmanship under normal use and service for a period of one year from the date of delivery by GRX to the first purchaser. If any such defect occurs during the warranty period, the aforesaid purchaser should communicate directly with GRX agent. If returned, GRX's agent will arrange for repairs or replacement within the terms of warranty. The defective instrument should be returned properly packed, freight prepaid. Loss or damage in shipment to GRX agent shall be at purchaser's risk. This same warranty is made for a period of thirty days with respect to the expandable parts.

In no event shall GRX be liable for any incidental, indirect, or consequential damages in connection with the purchase or use of the Radiant Warmer. This warranty shall not apply to, and GRX shall not be responsible for any loss arising in connection with the purchase or use of any such Radiant Warmer which has been altered by anyone other than an authorized GRX representative or altered in any way so as, in GRX's judgement, to affect its stability or reliability or which has been subject to misuse, negligence, or accident, or which has been used otherwise than in accordance with the instructions furnished by GRX. This warranty is in lieu of all other warranties, express or implied, and of all other obligations or liabilities on GRX's part, and GRX neither assumes or authorizes any representative or other person to assume for it any other liability in connection with the sale of such Radiant Warmer.

GRX disclaims all other warranties, express or implied, including any implied warranty of merchant ability or of fitness for a particular purpose or application other than those expressly set forth in the appropriate product labelling or user information manual.

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